Electronic Cigarettes Teleconference
Warning Letters and Letter to Industry

Moderator: Siobhan DeLancey
September 9, 2010
12:00 pm CT

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. During the question and answer session, please press star 1 on your touch-tone phones. Today's conference is being recorded. If you have any objections, you may disconnect at this time. Now I will turn the meeting over to Ms. Siobhan DeLancey. You may begin.

Siobhan DeLancey: Thank you very much, (Vicky). Welcome, ladies and gentlemen. This is Siobhan DeLancey from the FDA's Office of Public Affairs. This is an FDA teleconference for credentialed media to get more information on an FDA announcement about electronic cigarettes. This briefing is for credentialed media only.

One note, an incorrect version of the letter to the Electronic Cigarette Association was briefly posted this morning. The correct version has now been posted.

Our speaker today is Michael Levy, the Director of the Division of New Drugs and Labeling Compliance at the Center for Drug Evaluation and Research here at the FDA.

After Mr. Levy makes brief remarks, we'll receive questions from reporters. Reporters will be in a listen-only mode until we open the call up for questions. When asking a question, please be sure to state your name and your media affiliation and please limit yourself to one question only so that we can get to as many as possible.

The news release for this announcement has also been posted at FDA's Web site at fda.gov. I'll now turn the call over to Mr. Levy. Thank you.

Michael Levy: Good afternoon. We are announcing today that FDA sent warning letters to five distributors of electronic cigarettes for violations of the Federal Food, Drug and Cosmetic Act.

Also, in a letter to the Electronic Cigarette Association, FDA said the agency intends to regulate electronic cigarette and related products in a manner consistent with its mission of protecting the public health. The letter outlines the regulatory pathway for marketing drug products in compliance with the FDCA.

As many of you know, electronic cigarettes, or e-cigarettes, are products designed to mimic actual cigarettes and that deliver nicotine to the user in the form of a vapor. Although these products are frequently marketed to help consumers quit smoking, FDA has not evaluated them for safety or effectiveness.

As discussed in the letter to the Electronic Cigarette Association, for a drug to gain FDA approval, a company must demonstrate to the agency that the product is safe and effective for its intended use.

The company must also demonstrate the manufacturing methods are adequate to preserve the strength, quality and purity of the product. The agency has had discussions with firms that are interested in obtaining drug approval for e-cigarette products.

The companies receiving warning letters today are E-CigaretteDirect, LLC; Ruyan America, Inc.; Gamucci America, also known as Smokey Bayou, Inc.; E-Cig Technology, Inc.; and Johnsons Creek Enterprises, LLC.

The violations discussed in the warning letters issued today include marketing drugs in unapproved liquid form such as tadalafil, an erectile dysfunction drug, and rimonabant, a weight loss drug that has not been approved for use in the United States.

These liquid pharmaceuticals are designed to refill cartridges used in these cigarettes so that the drugs can be vaporized and inhaled. The violations cited today also include significant deficiencies in manufacturing practices, including failure to establish quality control and testing procedures required under the FDCA.

At this time, I'd be happy to answer your questions.

Siobhan DeLancey: Thank you, Mike. At this time, ladies and gentlemen, we'll take questions from credentialed media only.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question, please press star 1. You'll be prompted to record your name. To withdraw your request, press star 2. One moment.

Our first question comes from Jennifer Corbett of Dow Jones. You may ask your question.

Jennifer Corbett: Yes, hi, thanks for taking my question. Actually I have two, if possible. The first one I want to know is - or the first question I have is whether the products can stay on the market, you know, while you sort out the regulatory issues. And then I guess the other question is I understand there's a lot more e-cigarette companies, so I was just wondering if there'll be more warning letters forthcoming or if this is just being sent to a certain segment?

Michael Levy: Well, let me answer that in two ways. First of all, to address the products that we sent warning letters to today, the warning letters stipulate that the firms have 15 days to respond to them and so we're going to wait and evaluate the firms' responses before we decide how to follow up with those firms.

And as to, you know, e-cigarettes more broadly, you know, this action today concerns only the products that are outlined in the warning letters today.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from Michael Felberbaum of Associated Press. You may ask your question.

Michael Felberbaum: Thank you. Good afternoon. I was just trying to find out how does the action taking place today with the warning letters and the letter to the E-

Cigarette Association fit in with the pending lawsuit over the import and shipments of e-cigarettes?

Michael Levy: The pending litigation is not something that we can discuss today.

Siobhan DeLancey: Thank you. Next question.

Coordinator: Our next question comes from Molly Peterson of Bloomberg News.

Molly Peterson: Actually my question was just answered. Thank you.

Siobhan DeLancey: Thank you. Next question.

Coordinator: Our next question comes from Daniel DeNoon, WebMD.

Daniel DeNoon: Thank you for taking my question. The companies that are cited today are being cited for manufacturing quality controls, I understand, but also for saying that their intended use is for quit smoking. Other than - so are e-cigarette companies that don't make this claim included in this kind of warning to the e-cigarette manufacturers?

And just to follow up on the earlier question, can we expect more action against more of these companies?

Michael Levy: Well, we're going to continue to evaluate the marketers of e-cigarettes on a case-by-case basis. And as to the quit smoking claims that are made for these particular products, yes, we did consider that to be evidence that these particular products were intended to be used as drug/device combinations. However, that's not the only thing that we consider when we consider intended use.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from Malcolm Spicer of Elsevier Business Intelligence. Your line is open.

Malcolm Spicer: Yes, thank you. Mr. Levy, you mentioned that you are actually talking with some e-cigarette firms about new drug applications. Can you - what can you say about the progress or the status of those discussions and who are those firms?

Michael Levy: Unfortunately I can't discuss any details about those discussions today.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from Tom Maugh of L.A. Times.

Tom Maugh: The two companies that are marketing tadalafil and - or the one company marketing tadalafil and rimonabant, you're waiting 15 days before you do - take any actions against them also?

Michael Levy: Well, with those particular products, you know, we would expect the firm to stop marketing those products. If the firm does not stop marketing them, after 15 days we'll evaluate what to do.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from Emily Walker, MedPage Today.

Emily Walker: Hi. My question was sort of asked earlier but just to get a little more clarification on this. Is FDA only classifying these e-cigarettes as drugs because they specifically are saying that they can help people quit smoking? If they weren't making a quit smoking claim, would FDA classify e-cigarettes as drugs?

Michael Levy: Well, again, we consider those smoking cessation claims to be evidence of intended use, but it's not the only evidence that we consider in making a decision.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from (Heidi Splete), Pediatric News.

(Heidi Splete): Hi. Thanks for taking my call. I was just wondering what might be the message for pediatricians or adolescent medicine physicians if parents hear about this and have questions for the doctors. What would you say to doctors about this action?

Michael Levy: Well, to doctors, you know, what we'd like them to know is that these products are not proven safe and effective yet. There are FDA-approved smoking cessation aids on the market that are readily available.

You know, we do - we are interested in finding out whether e-cigarettes can be proven safe and effective and that's why we sent the letter today to the Electronic Cigarette Association.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from Michael Felberbaum of Associated Press.

Michael Felberbaum: Hi. I just wanted to clarify, on top of the warning letters, I mean, what does this mean for companies - other companies, and these companies as well, for selling e-cigarettes? Are you saying that they're - they should immediately stop selling them or, you know, or what exactly is the guidance from the FDA at this point?

Michael Levy: Well, we've - we have not made a decision to remove all e-cigarettes from the market. The action today really only concerns the products that are outlined in the warning letters.

You know, we did mention in the letter to the Electronic Cigarette Association that we are interested, again, in having firms that market these particular products and any similar products to meet with the agency about obtaining drug approval for them.

Siobhan DeLancey: Thank you. And I think we have time for one more question.

Coordinator: Our last question comes from Malcolm Spicer, Elsevier Business Intelligence. Your line is open.

Malcolm Spicer: Yes, thank you. As far as the additional evidence in addition to the quit smoking claims that you considered in make - in writing these letters, what was the additional evidence?

Michael Levy: Well, I think the letters are pretty specific in what evidence we use with these particular products.

Siobhan DeLancey: Thank you very much, Mr. Levy. And, ladies and gentlemen, this concludes today's media teleconference and thank you for your participation.

A replay will be available in about an hour and will be up for the next seven days. If you have follow up questions, please contact me, Siobhan DeLancey, at 301-796-4668. Thank you and good-bye.

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